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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,211	02/17/2004	Rainer Kuth	P03,0622	9905

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EXAMINER	
SEREBOFF, NEAL	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,211	KUTH ET AL.	
	Examiner	Art Unit	
	NEAL R. SEREBOFF	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/7/2008 has been entered.

Response to Amendment

2. In the Amendment dated 5/7/2008, the following has occurred: Claims 1 and 11 have been canceled; Claims 2 – 10 have been amended; Claim 12 has been added. Claims 2 – 10 and 12 are pending.

3. The Information Disclosure Statement (PTO-1449) submitted on 5/7/2008 has been considered.

Notice to Applicant

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 2 – 10 depend upon the newly added claim 12. For clarity, the rejection below of claim 12 precedes the rejections below of claims 2 - 10.

6. Within the remarks dated 5/7/2008, the Applicant did not challenge that a clinical trial administrator and the research entity commissioning the study can be the same. The Examiner notes that it is now Applicant Admitted Prior Art (AAPA) that a clinical trial administrator and the research entity commissioning the study can be the same.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 2 - 10 and 12 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). The process steps in claims (2 - 10 and 12) are not tied to another statutory class nor do they execute a transformation. Thus, they are non-statutory.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2 – 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 12 includes the new limitations "automatically generating and input program" and "a unique collection of input fields configured for entry."

- The Examiner finds no basis for automatic generation within the originally filed specification. In particular, Pre-Grant Publication paragraph 20 discusses how a practitioner, in conjunction with the software, generates the input fields.
- Regarding the unique collection of input fields, the Examiner finds nothing that could be defined as a unique collection. Additionally, given the information provided within Pre-Grant Publication paragraph 22, the Examiner finds that the input fields could be duplicated given the same or even given similar requirements.
- Claims 2 – 10 are rejected for the same reasons as they depend upon claim 12.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2 – 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 12 includes the limitations, "Automatically generating an input platform program that includes a unique collection of input fields configured for entry of the data that is necessary for a specific medical clinical study" and "Distributing said unique input platform program to each of a plurality of input locations that interface with respective patients participating in the specific medical clinical study."

- Regarding "unique input platform," the Examiner does not understand how the input platform is unique. The "unique" term of degree means one-of-a-kind (Good Word Guide, Unique) but the originally filed application does not require uniqueness. Additionally, given similar input criteria such as standard biometric data, the input

platform would be duplicated. Additionally, the Examiner does not understand by what factor is uniqueness determined?

- Regarding "respective patients," it is not clear from the claim where the patient has a respective relationship. Is the relationship between the patient and the input location or between the patient and the study?
- Claims 2 – 10 are rejected for the same reasons as they depend upon claim 12.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. ***Claims 12 and 9*** are rejected under 35 U.S.C. 102(e) as being anticipated by Tkaczyk et al., U.S. Pre-Grant Publication Number 2004/ 0059597.

15. As per claim 12, Tkaczyk teaches a method to input and store data for a medical clinical study, comprising the steps of:

- Automatically generating an input platform program that includes a unique collection of input fields configured for entry of the data that is necessary for a specific medical clinical study (paragraphs 26 and 35 – 48 where the template is used and other fields are automatically filled and further that the claimed data required is non-functional and therefore not limiting);

- Distributing said unique input platform program to each of a plurality of input locations that interface with respective patients participating in the specific medical clinical study (paragraph 37 where the information is presented on a web page);
- Upon interfacing at one of said input locations with one of said patients (figure 2, #14 and paragraph 30), entering a characteristic identifying that patient into a computer system at the input location and (paragraphs 38, 39 and 41, access where the patient label is non-functional), via the computer system (figure 2), automatically calling and activating said unique input platform program solely for said specific medical clinical study by entry of said characteristic (paragraph 42 where the options are limited to what is available);
- At said input location, providing data for said specific medical clinical study only by making entries in the respective data fields of the unique input platform program presented at the computer at the input location (paragraph 33 where the data is non-functional descriptive information and therefore has no patentable weight); and
- Storing the data entered via the unique input platform program (paragraph 33).

16. As per claim 9, Tkaczyk teaches the method of claim 12 as described above. Tkaczyk further teaches the method comprising, via said input platform, permitting only inputs that are required for said specific medical clinical study and that are incurred at the input locations that interface with respective patients participating in the specific medical clinical study (paragraph 26 where the fields are created to prompt a user to enter study information).

Claim Rejections - 35 USC § 103

17. ***Claim 2 – 8*** are rejected under 35 U.S.C. 103(a) as being anticipated by Tkaczyk et al., U.S. Pre-Grant Publication Number 2004/ 0059597 in view of Teshima, U.S. Patent Number 6,272,470.

18. As per claim 2 Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising distributing the input platform program in a framework of a medical data standard.

However, Teshima further teaches the method comprising distributing the input platform program in a framework of a medical data standard (column 1, lines 53 – 67 where the standard is DICOM).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

19. As per claim 3, Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising storing the input platform program in a region of the medical data standard reserved for patient data.

However, Teshima further teaches the method comprising storing the input platform program in a region of the medical data standard reserved for patient data (column 3, lines 8 – 15).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with

the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

20. As per claim 4, Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising storing the data acquired at an input location ensues in a data format that is determined by the input platform itself.

However, Teshima further teaches the method comprising storing the data acquired at an input location ensues in a data format that is determined by the input platform itself (column 14, lines 26 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

21. As per claim 5, Teshima in view of Thangaraj teaches the method of claim 4 as described above.

Tkaczyk does not explicitly teach the method comprising storing the acquired data in a framework of a medical data standard.

However, Teshima further teaches the method comprising storing the acquired data in a framework of a medical data standard (column 14, lines 26 – 34 where the standard is DICOM).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

22. As per claim 6, Teshima in view of Thangaraj teaches the method of claim 4 as described above.

Tkaczyk does not explicitly teach the method comprising storing the acquired data in a region of the medical data standard reserved for patient data.

However, Teshima further teaches the method comprising storing the acquired data in a region of the medical data standard reserved for patient data (column 11, lines 8 – 45 where the patient card contains patient data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

23. As per claim 7, Teshima in view of Thangaraj teaches the method of claim 2 as described above.

Tkaczyk does not explicitly teach the method comprising using the Digital Imaging and Communication in Medicine (DICOM) standard as the medical data standard.

However, Teshima further teaches the method comprising using the Digital Imaging and Communication in Medicine (DICOM) standard as the medical data standard (column 14, lines 26 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

24. As per claim 8, Teshima in view of Thangaraj teaches the method of claim 4 as described above.

Tkaczyk does not explicitly teach the method comprising distributing the input platform program in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DICOM) standard.

However, Teshima further teaches the method comprising distributing the input platform program in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DICOM) standard (column 14, lines 26 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to

provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

25. ***Claim 10*** is rejected under 35 U.S.C. 103(a) as being anticipated by Tkaczyk et al., U.S. Pre-Grant Publication Number 2004/ 0059597 in view of Thangaraj et al., U.S. Pre-Grant Publication Number 2003/ 02008378.

26. As per claim 10, Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising generating the input platform by a research entity commissioning the specific medical study.

However, Thangaraj teaches the method comprising generating the input platform by a research entity commissioning the specific medical study (paragraph 75 where the administrator sets up user functionality and paragraphs 82 and 83 that state that the clinical trial administrator is the same as the system administrator).

A clinical trial administrator and the research entity commissioning the study can be the same.

The Examiner therefore interprets the claim through this understanding (AAPA).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk.

- One of ordinary skill in the art would have added this feature into Tkaczyk with the motivation to create an Internet-based solution to clinical trial management (Thangaraj paragraph 5).
- The technical ability existed to add the Thangaraj feature into Tkaczyk as claimed and the substitution result is predictable.

Response to Arguments

27. Applicant's arguments, see 35 U.S.C. 112 1st paragraph, filed 5/7/2008, with respect to claim 11 have been fully considered and are persuasive. The 35 U.S.C. 112 1st paragraph rejection of claim 11 has been withdrawn.

28. In regard to the Applicant's interpretation of "clinical study," the Examiner notes that the narrow definition described by the Applicant is not defined within the Introduction. A clinical study may also be small, performed by a single physician out of a single office. However, the Examiner still maintains that the idea of a "clinical study" is non-functional and at best represents the further non-limiting intended use of the invention.

The Examiner's use of a reference that includes a "clinical study" was not to impart any functionality on "clinical study" but to merely to limit the number references used within the previous rejections. For example, the Examiner was able to use the same reference for storing the data within DICOM format even though the usage of the DICOM format is a matter of non-limiting design choice (MPEP 2144). Changing the data into a standard format other that DICOM, does not change the functionality of the claimed method. The Applicant admits this within the Background of the Invention, paragraph 4 by stating, "It suffices that specific information exists in a standardized format for transmission and storage, for example, address information, information about the data type, etc. An example of such a standard is the DICOM standard."

Also within the Background of the Invention section, "An Internet-based method to implement a clinical study is specified in German patent document DE 100 22 039, in which study forms are made available worldwide from a central server (study server) to arbitrary locations after an

authorization check." The Examiner notes here that priority invention allows forms to be available after an authorization check. The "study" could also be for a survey of shopping habits or a poll.

29. Applicant's arguments with respect to claims 1 - 11 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner notes that the claimed method is similar to creating a web page based upon template material. That web page could also be an informed consent form as described in Califano et al., U.S. Pre-Grant Publication 2003/ 0033168. The Examiner notes that this reference, although not currently applied, anticipates claim 12. Any potential future amendments should be made with regard to Califano also anticipating claim 12.

In general, dynamically creating web based forms based upon user input is old and well known and multiple examples of this exist within prior art. Further, limiting access to forms is old and well known and multiple examples exist within the prior art. Even if these examples were not specifically for a medical study, the Examiner would find ample reasons to make these combinations. The Examiner suggests that the Applicant further consider potential future amendments in view of recent US Supreme Court decisions and Court of Appeals for the Federal Circuit decisions.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stefanescu et al., U.S. Pre-Grant Publication Number 2003/ 0013951

Brummel et al., U.S. Pre-Grant Publication Number 2002/ 0035487

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
7/10/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626